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MAIL STOP APPEAL BRIEF-PATENTS
Attorney Docket 0508-1018
PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE
THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Jean PLOUET et al.

Serial No. 09/091,561

Filed August 21, 1998

Appeal No. _____

GROUP 1644

Examiner G. Ewoldt

ANTI-IDIOTYPIC ANTIBODIES OF
VASCULAR ENDOTHELIAL GROWTH FACTOR
AND USE THEREOF AS DRUGS

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REPLY BRIEF

MAY IT PLEASE YOUR HONORS:

This is in response to the Examiner's Answer dated
July 15, 2003.

It is respectfully submitted that the Examiner's
Answer underscores the fact that the Examiner has
erroneously rejected claims 25-30 and 32-35 under 35 USC
112, first paragraph, for allegedly containing subject
matter not described in the specification in such a way as
to enable one skilled in the art to make and use the present
invention.

The uncontroverted evidence of record establishes
that the present specification enables one skilled in the
art how to make and use the claimed invention in either
polyclonal or monoclonal form. Moreover, the present
specification clearly enables one skilled in the art on how

to produce and use the Fab fragments of the claimed invention.

In imposing and maintaining the enablement rejection, the Examiner believes that the present specification would only result in a polyclonal anti-serum. The Examiner then contends that only a monoclonal antibody can function in the intended capacity of the claimed invention. The Examiner states that "unless the claimed antibody is separated from the other antibodies in the polyclonal antiserum, the claims are akin to claims reciting blue paint in a bucket of green paint". This analogy, while colorful, does not comport with the legal, scientific, and technical issues involved in the claimed invention.

The claimed invention is broadly directed to an antibody which is a ligand of the KDR/flk-1 receptor yet not a ligand of the flt-1 receptor. The claims do not limit the antibody to a polyclonal or a monoclonal antibody. Moreover, the claimed invention does not require that the antibody be isolated or purified to homogeneity.

The claimed antibody is indisputably present in the polyclonal antiserum described in the present specification. That only 15-20% of immunized rabbits

were found to produce the claimed antibody does not bear on the enablement issue; the fact remains that the claimed antibody was produced, and its production is taught by the specification in a reproducible manner. In fact, the present specification teaches that the claimed antibody is present in a Ig2 J fraction at a concentration level at which one of ordinary skill in the art can readily detect the claimed antibody (Figures A and B submitted with the declaration of Dr. Plouet filed on March 25, 2002).

Moreover, it is clear that the present specification teaches how to produce and sufficiently purify the claimed antibodies so that one can conduct screening and biological activity studies (present specification, pg. 10, line 1 to pg. 21, line 18). The experiments in the present specification demonstrate that the Ig2 J fraction promotes tumor angiogenesis and is valuable as a selective targeting agent (present specification, pg. 21, line 10 to pg. 24, line 1; and confirmed by Declaration by Dr. Plouet filed on March 25, 2002). Thus, contrary to the Examiner's opinion, the claimed specification does teach how to make and use the claimed antibody.

As to monoclonal antibodies, one of ordinary skill in the art would already possess the requisite skills,

incentive, and knowledge to conduct the additional protocols, screening and isolation steps to produce a monoclonal antibody. The declarations filed on March 25, 2002 by Dr. Plouet, Dr. Fons and Dr. Cazenave evidence this point. Nevertheless, the Examiner considers that the present disclosure is not enabling because the present specification does not bodily include additional steps to produce a monoclonal antibody.

However, it is well settled that a patent need not teach, and preferably omits, what is well known in the art. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F. 2d 1524, 3 USPQ2d 1737 at 1743 (Fed. Circ 1997). Plainly, no additional steps are needed to teach the novel aspects of the invention, and hence the specification constitutes adequate enablement.

Against this backdrop, the Examiner merely alleges that additional steps are required. The Examiner fails to substantiate why one of ordinary skill in the art would not be in possession of the requisite skills to produce a monoclonal antibody in accordance with the claimed invention. Indeed, upon reviewing the Examiner's Answer and Official Actions issued in the present application, it is clear that the Examiner himself is cognizant of and quite

familiar with the conventional steps used to produce a monoclonal antibody.

The Examiner also believes that the Fab fragments of the claimed invention are not enabled by the present disclosure. Claims 27 and 28 are directed to the Fab fragments of the anti-idiotypic antibodies of claims 25 and 26, respectively. As noted by the Examiner, Fab fragments are an enzymatic cleavage product of an antibody. As a cleavage product, it is believed to be apparent that the claimed Fab fragments would not and do not exert the same functional activities of an antibody (e.g., dimerization, internalization and self-proliferation).

As to the production of the Fab fragments, the specification clearly teaches how to produce these Fab fragments (present specification, pg. 9, lines 13-20 and pg. 13, lines 17-20). In view of the above, it is believed that the Fab fragments are supported by the present disclosure.

As to the Examiner's objections to the Summary of the Invention, appellants traverse the assertion that this section of the brief is deficient. While the Examiner may prefer a more detailed Summary of the Invention, appellants believe that the Summary of the Invention provides a

satisfactory and concise explanation of the claimed invention.

Appellants agree that the passage in the present specification at page 8, lines 3-21 relates to how the claimed invention was made. This page is cited as appellants believe that it is important to know how the antibodies of the present invention were discovered to understand the claimed invention.

As to the capabilities of the claimed invention, they aid in explaining the nature of the claimed invention. Contrary to the Examiner's assertions, the present specification does state that the claimed anti-idiotypic antibodies are capable of treating pathologies involved in angiogenesis and neovascularization (present specification, pg. 2, line 20 to pg. 3, line 15).

The Examiner is correct in stating that the passage in the present specification at page 3, lines 1-23 is directed to the anti-idiotypic antibodies of the claimed invention. Rather, the claimed Fab fragments are first mentioned in the present specification on page 4, lines 1-4. The Fab fragments are then further discussed at page 9, line 13 to page 10, line 1.

Finally, the claims do not stand or fall together. Claims 25-26, 29-30, 32-33 and 35 are patentable independently of claims 27, 28 and 34. Indeed, the specification and declarations filed in the present application address and describe the Fab fragments separate from the anti-idiotypic antibodies of the claimed invention (e.g., present specification, pg. 9, lines 13-20). While the Examiner considers that antigen binding fragments are not patentably distinct from antibodies, the Examiner once again fails to provide any evidence to support this opinion.

In summary, it is believed that the Examiner erroneously rejects claims 25-30 and 32-35 under 35 USC 112, first paragraph. It is believed that none of the rejections on appeal merit affirmance by the Board, but instead must be reversed. Such action is accordingly respectfully requested.

Respectfully submitted,

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